August 5, 2019

Ms. Monet Vela
Regulations Coordinator
Office of Environmental Health Hazard Assessment
1001 "I" Street
Sacramento, CA 95812

Submitted electronically to P65Public.Comments@oehha.ca.gov

RE: Proposed Amendments to Title 27, California Code of Regulations Section 25821(a): "Calculating Intake by the Average Consumer of a Product"

Dear Ms. Vela:

The California Chamber of Commerce, Grocery Manufacturers Association and the below-listed organizations (hereinafter, "Coalition") thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment's ("OEHHA") Proposed Amendment to Title 27, California Code of Regulations Section 25821(a). Our Coalition consists of California-based and national organizations and businesses of varying sizes that, collectively, represent nearly every major business sector that would be directly impacted by OEHHA's proposed regulation.

The Coalition supports OEHHA's decision to not proceed with the amendment to Section 25821(c)(2) that OEHHA had proposed on October 5, 2018 ("Arithmetic Mean Proposal"). For the reasons the Coalition specified in its December 3, 2018 letter, which the Coalition incorporates by reference, the Arithmetic Mean Proposal would be inconsistent with Proposition 65's average exposure-based approach to warnings and would place significant burdens and litigation risk upon businesses.

For the same reasons, OEHHA should not proceed with proposed Section 25821(a) ("Average Concentration Proposal"). The Coalition appreciates OEHHA's efforts to modify the prior proposal to clarify its application to agricultural producers and upstream ingredient suppliers of manufacturers. Yet the modification does not ameliorate the vast extent of the burdens, costs, and litigation risks that affected the prior proposal. Moreover, the Average Concentration Proposal is ambiguous in key respects, which adds uncertainty and risk.

OEHHA should not adopt the Average Concentration Proposal.

1. The Average Concentration Proposal Is Inconsistent with Proposition 65's Average Exposure-Based Approach to Warnings.

The longstanding principle behind Proposition 65's exposure-based approach is that warnings for consumer products are based on the "reasonably anticipated rate of exposure" by "average users." 27 Cal. Code Regs. § 25821(c)(2). The exposure level is a product of both the

concentration level and intake rates. 27 Cal. Code Regs. § 25821(b). The "level in question" must be determined by estimating the typical concentration of the chemical in a product. As the Coalition explained in its prior comment letter, OEHHA is incorrect in arguing that the level in question must be evaluated on an individual, as opposed to an average and typical basis. Nothing in the statute or the existing regulations contemplates warning on an individual-by- individual basis. In fact, the regulations directly contradict OEHHA's interpretation. OEHHA's interpretation cannot be a justification for the Average Concentration Proposal.

An absolute prohibition on averaging of concentration results across different facilities will often lead to unreliable estimates of typical concentration levels for purposes of Proposition 65. The only way the level of exposure can reflect the reasonably anticipated rate of exposure is if concentration levels also reflect what is typical. This exercise is not amenable to an absolute prohibition on cross-facility averaging, which draws the line at variability at the facility level in all cases. Just as a single product pulled from a shelf for testing or a single lot does not necessarily reveal typical concentration levels because of variability in test results, the levels in an individual unit produced at a particular facility may not be typical of the product as a whole if it is made in multiple facilities. For example, a manufacturer may ship for distribution a food product made at Facility A one week and the next week ship the same product made at Facility B. Isolating a single facility in that instance will not capture typical exposure levels to average users.

OEHHA clarifies that it does not intend for the Average Concentration Proposal to extend upstream of the manufacturer to cover foods or ingredients supplied to it. For example, if a food manufacturer uses ingredients or foods supplied to it to make a finished product at a particular facility, the prohibition on cross-facility averaging does not prohibit the food manufacturer from averaging concentration results of the finished products that it makes with those ingredients (even if the upstream suppliers use multiple facilities). Thus, the Average Concentration Proposal rests on an assumption that variability in reproductive toxicants affects the food supply simply by virtue of a food manufacturer making a food product across two different facilities. This assumption is wrong and cannot serve as a justification for the proposal.

First, facility equipment is not a factor that typically affects concentration levels of reproductive toxicants in foods. Food manufacturing facilities must meet Good Manufacturing Practices ("GMPs") for their operations under 21 C.F.R. Part 110. GMPs specify methods, equipment, facilities, and controls for producing processed foods for food safety. U.S. FDA guidance also specifies that food facilities should follow Hazard Analysis & Critical Control Points ("HACCP") plans.[1] HACCP plans are designed to avoid chemical, microbiological, and physical hazards in food production and address not only processing and manufacturing of food but also raw materials used by food manufacturing facilities. Indeed, OEHHA has not identified any issue with contamination of reproductive toxicants through facility equipment or the processing and manufacturing aspects of food production, let alone high degrees of variability in those levels. Nor could it do so.

[1] https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm.

Second, there is variability of substances in food ingredients *even when a product is made at the same facility.* OEHHA has never provided any data establishing that the level of variability of any contaminants in foods produced at multiple facilities is significantly greater than when the food is made at a single facility. OEHHA simply assumes that there is an unacceptable degree of variability -- in all instances -- in contaminants when a food is manufactured across multiple facilities than when it is made in a single facility.

We recognize that there may be instances in which it is not appropriate to average concentration results across facilities. The possibility that it may not be appropriate in certain instances does not mean, however, that OEHHA must prohibit it in all instances, thereby distorting the relevant exposure level for many other products or businesses. Courts are fully capable of considering any relevant factors that affect how and whether to average across facilities under the facts of a case, and courts are well-equipped to address evidentiary and statistical issues involving the characterization of variable data sets. *See, e.g.*, *Environmental Law Found. v. Beech-Nut Nutrition Corp.*, 235 Cal. App. 4th 307 (2015).

The Average Concentration Proposal presents an entirely new regulatory requirement that will affect businesses in compliance efforts and in litigation. Not only is there no showing of any actual need for this proposal (let alone a showing of any actual need that justifies the costs and burdens), the proposal runs counter to Proposition 65's average exposure-based approach to warnings.

2. The Proposal Creates Unnecessary and Significant Costs and Burdens and will Exacerbate the Overwarning Problem.

The Average Concentration Proposal still presents many of the same problems as OEHHA's October 2018 proposal. First, there may be manufacturers that use the *same* ingredients from the *same* sources across different facilities. The manufacturers cannot average the concentration results across the two facilities in that instance, which makes little sense given that chemicals are very unlikely to be added in processing at the facility level. Yet to determine the level of exposure under OEHHA's proposal, the manufacturer would have to increase testing to test samples made at both facilities, which would raise costs. For example, if even 15 percent of the approximately 90,000 FDA-registered domestic manufacturing facilities are owned by the same company and manufacture at least one product across two facilities, the testing costs alone are significant.[2] The additional costs of testing three samples per year may total over $40 million (assuming testing costs are $1,000 per sample). This does not include additional costs associated with supply chain changes needed to ensure predictable concentration levels, additional personnel costs, or other compliance-related costs. Nor does it account for lost revenues and employment that may be borne across the food supply chain if manufacturers consolidate facility production or agricultural suppliers.

[2] There are over 150,000 FDA-registered food manufacturing facilities when including international facilities. https://www.fda.gov/food/registration-food-facilities/food-facility-registration-statistics.

Moreover, although OEHHA has clarified that the "level in question may be based on the concentration of the chemical in a food product as it is offered for sale to the end consumer, even if that product contains ingredients sourced from different manufacturers or producers," as a practical matter, this clarification does not avoid impacts to the agricultural community. For example, a food manufacturer may make a product at two facilities and receive different ingredients from different suppliers and regions based on regional agricultural supply. To ensure a predictable concentration level across facilities, certain ingredients may need to be transported to other more distant facilities, which increases transportation costs and has adverse environmental impacts. Alternatively, a manufacturer may decide to consolidate the agricultural suppliers it uses to reduce testing costs and to reduce variability in concentration levels stemming from the use of different ingredient sources.

In addition to these compliance-related costs, OEHHA's proposal would add yet another burden upon a defendant's already disproportionately heavy burden of proof in Proposition 65 litigation. Unlike many other laws, Proposition 65 sets exposure thresholds, not concentration thresholds. A plaintiff does not need to prove the exposure level for its liability case. A business defendant carries the burden on these elements. For the warning exemption in Section 25249.10(c), a defendant must prove (1) the concentration level in question and (2) the reasonably anticipated rate of intake or exposure to "average users." (If OEHHA has not published a "safe harbor" warning threshold, a defendant must additionally prove this threshold.)

This exposure-based approach to regulation poses a significant challenge to companies because it is often not readily apparent if the amount of a chemical in a food results in an exposure above the threshold. Instead, this exercise typically requires a technical exposure assessment. Even if a company goes through with this technical exercise and determines that an exposure does not exceed the warning threshold, the lack of bright-line, clear standards around these elements makes it easy for a Proposition 65 enforcer to dispute this determination, raising the prospect of costlier litigation -- often at trial -- to prove the exposure exemption. This ambiguity is settlement leverage for plaintiffs and can lead to litigation abuse.

With the Average Concentration Proposal, OEHHA would add a new element to this already-complicated burden of proof: a defendant would have to prove—in all cases—the level in question on a facility-by-facility basis. As discussed above, there is no factual support provided by OEHHA for an assumption that *in all cases* cross-facility production of the same product by the same manufacturer will result in significant variability in concentration levels. Moreover, OEHHA is not proposing a corresponding amendment in Section 25903 to limit the scope of an enforcer's Proposition 65 notice or litigation to the product *as manufactured at a specific facility*. If OEHHA's assumption that concentration levels vary facility-to-facility and that certain facilities may have low concentration levels while others have higher levels, then a plaintiff's testing result for its claim must be specific to that facility. Otherwise, this new burden proposed by OEHHA exacerbates the burden of proof disparities faced by defendants in litigation and adds another layer of uncertainty and risk to a defendant's burden of proof.

Many businesses are likely to choose to warn, even when warnings are not necessary, as a way to avoid costly enforcement actions, and as OEHHA knows, such overwarning can have a negative

impact on public health as well as the public's confidence in Proposition 65 warnings generally. If OEHHA advances the Average Concentration Proposal, it should propose a regulation to limit the scope of a plaintiff's Proposition 65 claim to the product specific to the facility and manufacturer that produced it.

More fundamentally, as requested in the Coalition's December 2018 comment letter, if OEHHA intends to advance this proposal, OEHHA must first conduct a cost analysis and provide evidence of an actual need for this proposal that justifies the costs and burdens to businesses. A basic tenet of reasoned rulemaking is that a proposed regulation addresses an actual need for the regulation and the agency has considered the costs and benefits of the regulation before advancing it. OEHHA has not demonstrated either of these elements.

3. The Proposal Is Ambiguous and Uncertain.

The Average Concentration Proposal is ambiguous, which will lead to uncertainty, litigation risk, and overwarning. If OEHHA elects to move forward with this proposal over the significant concerns and objections raised above, we offer these observations.

We understand that OEHHA does not intend for the Average Concentration Proposal to extend upstream to food producers (growers) or to food processors that receive agricultural commodities from producers and process them through milling, husking, hulling, pasteurizing, and other processing activities. If so, OEHHA should make this exclusion clear in the final statement of reasons. As proposed, the term "manufacturer" could potentially be read to cover such processors. For example, a number of agricultural commodities processed by food processors may be shipped in essentially final form to downstream customers that, in turn, package and sell the products under the customers' own brands and packaging (without further manufacturing). This is the case with certain agricultural products that undergo minimal processing such as raw, unroasted almonds. To avoid confusion on this issue, OEHHA should clarify that the proposed prohibition on cross-facility averaging applies only to *manufactured* food products sold in final consumer packaging (such as Brand X peaches) and does not apply to foods that are *processed* by agricultural processors. OEHHA should also specifically embrace FDA's definition of "facility" located at 21 C.F.R § 1.227 to avoid any unnecessary debate.

In addition, if OEHHA advances this proposal, it is not appropriate for OEHHA to prohibit averaging across facilities for foods "packaged" in "different manufacturing facilities." A food product may be manufactured at a single facility but packaged in other facilities. It may be packaged in different types of packaging at the same facility, or it may be packaged in the same type of packaging at different facilities. The proposal could be read to prohibit the business from averaging concentration levels of the product merely because it is packaged at "different manufacturing facilities," regardless of whether there is any variability in the concentration levels of any listed chemicals in the packaging that corresponds to facilities. This makes no sense, and in any event it is unnecessary because packaging tends to be largely consistent and uniform. And, as noted above, there is no evidence that contamination is added to foods through facility equipment, including packaging equipment used in facilities.

Thus, in addition to the clarifications requested by the Coalition for any final statement of reasons, the following edits to the text should be made to add clarity that the regulation applies only to final manufactured food products offered for sale in the consumer packaging.

> (a) For purposes of the Act, "level in question" means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible, and does not include exposure to a listed chemical from any other source or product. Where a business presents evidence for the "level in question" of a listed chemical in a manufactured food product based on the average of multiple samples of that food, the level in question may not be calculated by averaging the concentration of the chemical in manufactured food products from different manufacturers, or that were manufactured ~~or packaged~~ in different manufacturing facilities from the manufactured product at issue. The level in question may be based on the concentration of the chemical in a food product as it is offered for sale to the end consumer in its final consumer packaging, even if that product contains ingredients sourced from different manufacturers, processors, or producers.

* * *

OEHHA's Average Concentration Proposal would exacerbate the already abusive Proposition 65 litigation climate, further increase consumer alarm and confusion about Proposition 65 warnings, significantly decrease business certainty, and dramatically increase compliance costs and defense costs for businesses of all sizes without any showing of why this proposal is necessary. Ultimately, it should be left to businesses -- who bear the heavy burden of proof -- to decide the most appropriate way to obtain representative concentration levels on a case-by-case basis, to make their own compliance determinations, and to be prepared to defend those determinations in court if challenged. For some businesses, this may indeed mean single-facility testing, but this is not a question that can be answered correctly by a "one-size-fits-all" rule.

OEHHA should not adopt this proposal.

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Thank you for considering our comments.

Sincerely,

Adam Regele, Policy Advocate
California Chamber of Commerce

John Hewitt, Director of State Affairs
Grocery Manufacturers Association

On behalf of the following organizations:

Almond Alliance of California
American Bakers Association
American Beverage Association
American Herbal Products Association
American Chemistry Council
Associated Roofing Contractors of the Bay Area Counties
Association of California Egg Farmers
California Apartment Association
California Business Properties Association
California Cotton Ginners and Growers Association
California Farm Bureau Federation
California Fresh Fruit Association
California Fuels & Convenience Alliance
California Grocers Association
California Hospital Association
California League of Food Producers
California Manufacturers & Technology Association
California/Nevada Beverage Association
California Pear Growers Association
California Retailers Association
California Seed Association
Can Manufacturers Institute
Chemical Fabrics & Film Association
Chemical Industry Council of California
Consumer Healthcare Products Association
Consumer Specialty Product Association
Copper & Brass Fabricators Council
Council for Responsible Nutrition
Del Monte Foods, Inc.
Family Winemakers of California
Grower-Shipper Association of Central California
Monterey County Farm Bureau
National Confectioners Association
National Council of Textile Organizations
National Electrical Manufacturers Association
National Federation of Independent Business
Natural Products Association
Oxnard Chamber of Commerce
Pacific Coast Producers
Personal Care Products Council
Plastics Industry Association
Redondo Beach Chamber of Commerce and Visitors Bureau
Seneca Foods Corporation
South Bay Association of Chambers of Commerce

Southwest California Legislative Council
Styrene Information and Research Center
USANA
Ventura Agricultural Association
Western Agricultural Processors Association
Western Growers Association
Western Plant Health Association

cc: Jared Blumenfeld, Secretary, CalEPA
Julie Henderson, Deputy Secretary for Health and Public Policy, CalEPA
Lauren Zeise, Director, OEHHA
Allan Hirsch, Chief Deputy Director, OEHHA
Carol Monahan-Cummings, Chief Counsel, OEHHA
Mario Fernandez, Staff Counsel, OEHHA
Christine Hironaka, Deputy Cabinet Secretary, Office of the Governor